

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-159

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-159

Medicis Pharmaceutical Corporation
Attention: Mitchell S. Wortzman, Ph.D.
Executive Vice President
Research and Development
8125 North Hayden Road
Scottsdale, Arizona 85258

Dear Dr. Wortzman:

Please refer to your new drug application (NDA) dated August 30, 1999, received September 8, 1999, submitted under section 505(b) pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Loprox (ciclopirox) Shampoo, 1%.

We acknowledge receipt of your submissions dated August 29, September 19, October 23 and November 21, 2002; February 6, 8, 10, 14, 21 and 26 (3 facsimiles), 2003.

The August 29, 2002, submission constituted a complete response to our September 6, 2000, action letter.

This new drug application provides for the use of Loprox (ciclopirox) Shampoo, 1%, for the topical treatment of seborrheic dermatitis on the scalp in adults.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved NDA 21-159." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated February 10, 2003. The commitment is listed below.

1. The applicant commits to conducting an alternative, dermal carcinogenicity study in transgenic mice (b)(4)----- with the ciclopirox shampoo, 1%.

Protocol Submission:	Within 4 months of the date of this letter
Study Start:	Within 6 months of the date of the approval of protocol
Final Report Submission:	Within 12 months after study completion

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should

include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatologic and Dental Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

If you have any questions, call Jacquelyn Smith, Regulatory Project Manager, at (301) 827-2020

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Jonathan Wilkin
2/28/03 11:07:33 AM

APPEARS THIS WAY
ON ORIGINAL